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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,616	07/02/2001	Aprile L. Pilon	116142/00170	3118

31013 7590 09/15/2003

KRAMER LEVIN NAFTALIS & FRANKEL LLP
INTELLECTUAL PROPERTY DEPARTMENT
919 THIRD AVENUE
NEW YORK, NY 10022

EXAMINER

KAPUST, RACHEL B

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/898,616

Applicant(s)

PILON ET AL.

Examiner

Rachel B. Kapust

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-100 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-100 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-34, drawn to a bacterial expression system for production of recombinant human uteroglobin (rhUG), classified in class 435, subclass 69.1, 71.2, 243 or 260.
- II. Claims 35-55 and 74-78, drawn to a method of purifying rhUG and determining the purity of rhUG, classified in class 530, subclass 412.
- III. Claims 56-72, drawn to an assay for determining the potency of rhUG, classified in class 435, subclass 7.1 or 7.8.
- IV. Claim 73, drawn to a method for measuring *in vitro* the binding of rhUG to fibronectin, classified in class 435, subclass 7.8.
- V. Claims 79-100, drawn to a pharmaceutical composition comprising rhUG, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Group I is distinct from Group II because the method of Group II does not required the processes and steps of Group I. The purification method of Group II can be applied to other unrelated sources. Group I is not related to Group III because the expression system cannot be used in the assay method, and the expression methods have different steps, goals and outcome measures from the assay. Group I is not related to Group IV because the expression system of Group I cannot be used in the binding assay of Group IV, and the expression methods have different steps, goals, and outcome measures from the binding assay. Group I is not related to Group V because the synthetic gene of Group I is not related to the protein of Group V. They differ structurally and functionally and cannot be used together or interchangeably.

Group II is not related to Groups III and IV. The methods require different reagents and different method steps, and have different goals and different outcome measures. Group II is distinct from Group V. The pharmaceutical composition of Group V can be purified in other ways such as by *in vitro* synthesis or a peptide synthesizer.

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Group III is not related to Group IV. The methods require different reagents and different method steps, and have different goals and different outcome measures. Group III is distinct from Group V. The pharmaceutical composition of Group V can be assayed in other ways, such as by monitoring fibronectin binding.

Group IV is distinct from Group V because the methods are drawn to different conditions and thus have different goals and different outcome measures. Group IV is distinct from Group V. The pharmaceutical composition of Group V can be assayed in other ways, such as by phospholipase A₂ activity.

Because these inventions are distinct and/or unrelated for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the searches required for the different groups are dissimilar from each other, restriction for examination purposes as indicated is proper.

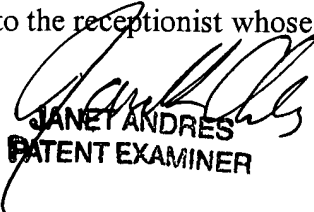
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (703) 305-0634. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RBK


JANET ANDRES
PATENT EXAMINER